Co-trimoxazole tablets 80/400mg (Trimethoprim and Sulfamethoxazole)

What in this leaflet

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2 What you need to know before you take Co-trimoxazole tablets
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1 What Co-trimoxazole tablets are and what they are used for

Co-trimoxazole 80 mg/400 mg Tablets (called ‘Co-trimoxazole tablets’ in this leaflet) are made up of two different medicines called sulfamethoxazole and trimethoprim. Both belong to a group of medicines called antibiotics. They are used to treat infections caused by bacteria, such as infections caused by bacteria called pneumocystis jiroveci — infections caused by bacteria called Toxoplasma gondii and infections caused by bacteria called Treponema pallidum.

Co-trimoxazole tablets are used in infants and children over 12 years. Co-trimoxazole tablets can be used to treat or prevent:

• lung infections (pneumonia or PCP) caused by a bacteria called pneumocystis jiroveci — infections caused by bacteria called Toxoplasma gondii and infections caused by bacteria called Treponema pallidum
• bladder or urinary tract infections (water infections)
• infections caused by a bacteria called Toxoplasma (toxoplasmosis)
• lung infections such as bronchitis
• certain bacterial infections of the skin, eyes and ears
• certain bacterial infections of the mouth and throat
• certain viral respiratory infections
• bacterial meningitis
• certain sexually transmitted infections such as syphilis and gonorrhoea
• bacterial skin infections such as boils and carbuncles
• other infections caused by different bacteria

2 What you need to know before you take Co-trimoxazole tablets

Do not take Co-trimoxazole tablets if:

• you are allergic (hypersensitive) to sulfamethoxazole, trimethoprim or Co-trimoxazole
• you are allergic to any of the other ingredients of Co-trimoxazole tablets (see section 6)

In the UK, certain antibiotics, such as penicillins and cephalosporins, are used to treat pneumonia caused by bacteria called pneumocystis jiroveci. If you are allergic to any of these antibiotics, you cannot take Co-trimoxazole tablets.

Co-trimoxazole tablets are not usually used to treat PCP unless you are HIV positive.

You should not take Co-trimoxazole tablets if you:

• have had a previous allergic reaction to Co-trimoxazole or any of the ingredients of Co-trimoxazole tablets
• you have had a blood problem, such as blood disorders or blood problems related to the use of certain antibiotics, such as penicillin or cephalosporins
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Co-trimoxazole tablets are usually used to treat certain infections of the skin, eyes or ears, such as infections caused by different bacteria. If you are allergic to any of these, you cannot take Co-trimoxazole tablets.

You should not take Co-trimoxazole tablets if you:

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3 How to take Co-trimoxazole tablets

Follow the instructions on the pack. These may differ from those in this leaflet.

Co-trimoxazole tablets come in 28 tablets, which should be taken once a day. The tablets can be taken whole or crushed, but not chewed.

Co-trimoxazole tablets can be taken with or after food.

You should take the tablets with a glass of water. Do not take them on an empty stomach.

If you are sick (nausea) or having diarrhoea. Although it is better to take them with food, you can still take them on an empty stomach. Do not take them at the same time as any other medicine, such as other antibiotics.

You can take Co-trimoxazole tablets with or without food. However, some other medicines work. Also some other medicines can affect the way Co-trimoxazole tablets work.

This includes herbal medicines. This is because Co-trimoxazole tablets can affect the way some medicines work. Also some other medicines can affect the way Co-trimoxazole tablets work.

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4 Possible side effects

Like all medicines, Co-trimoxazole tablets can cause side effects, although not everyone gets them.

The most common side effects of Co-trimoxazole tablets are:

• bruising or bleeding
• skin reactions — if you develop a rash or any of the following symptoms, seek medical advice immediately: redness of your skin, difficulty breathing, swelling of your lips, face, eyes or penis, severe allergic reactions such as anaphylaxis, high fever, blisters, ulcers in your mouth, nose, throat or genitals, skin ulceration and blistering
• liver or kidney problems
• jaundice, which can cause yellowing of your skin or the whites of your eyes
• you have a problem with your blood causing bruising or bleeding
• you are underweight or malnourished
• you have been told by your doctor that you have a lot of protein in your blood

If you get any side effects, talk to your doctor or pharmacist. You may need to stop taking Co-trimoxazole tablets before taking them again.

5 How to store Co-trimoxazole tablets

Keep out of the reach of children.

Store in an aerial, cool place.

Do not store in the bathroom. Do not freeze.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

6 Contents of the pack and other information

Pack size:

• 28 tablets

What to do if you think you have taken too much Co-trimoxazole tablets

If you take too much Co-trimoxazole tablets, talk to your doctor or pharmacist for advice.

What to do in an emergency (Overdose)

In case of overdose or accidental ingestion, seek medical advice immediately.

If you are going to have surgery or dental treatment, tell the surgeon or dentist that you are taking Co-trimoxazole tablets.

What to do if you miss a dose

Take the missed dose as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and take your next dose at the usual time. Do not take a double dose.

What you need to know before you take Co-trimoxazole tablets

• What is in this leaflet
• Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
• Keep this leaflet. You may need to read it again.
• If you have any further questions, ask your doctor or pharmacist.
• This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if these signs of illness are the same as yours.
• If you get any side effects, talk to your doctor or pharmacist.
• This includes any possible side effects not listed in this leaflet. See section 4.

Who should not take Co-trimoxazole tablets

Do not take Co-trimoxazole tablets if:

• you are allergic (hypersensitive) to sulfamethoxazole, trimethoprim or Co-trimoxazole
• you have been told that you have a problem with your blood causing bruising or bleeding

In the UK, certain antibiotics, such as penicillins and cephalosporins, are used to treat pneumonia caused by bacteria called pneumocystis jiroveci. If you are allergic to any of these antibiotics, you cannot take Co-trimoxazole tablets.

Co-trimoxazole tablets are not usually used to treat PCP unless you are HIV positive.

You should not take Co-trimoxazole tablets if you:

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• you have had a blood problem, such as blood disorders or blood problems related to the use of certain antibiotics, such as penicillin or cephalosporins
**How to take Co-trimoxazole tablets**

Always take the medicine exactly as described in the leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**The recommended dose is:**

<table>
<thead>
<tr>
<th>Age</th>
<th>Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;12 years</td>
<td>STANDARD DOSAGE</td>
</tr>
<tr>
<td>&gt;12 years</td>
<td>2 Tablets every 12 hours</td>
</tr>
</tbody>
</table>

**Children under 12 years**

The schedules for children are according to the child’s age and body weight provided in the table below:

<table>
<thead>
<tr>
<th>Age</th>
<th>Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;2 years</td>
<td>3 Tablets every 16 hours</td>
</tr>
<tr>
<td>&gt;8 years</td>
<td>2 Tablets every 12 hours</td>
</tr>
</tbody>
</table>

- **Co-trimoxazole should be taken for at least five days.**
- **Children** should be given the correct dose of Co-trimoxazole which your doctor has prescribed.
- **Co-trimoxazole 160 mg/800 mg Tablets** are not usually given to children under 12 years old.if they have been given to your child under 12 years please speak to your doctor or pharmacist for more information.

**Special Dose**

The dose of Co-trimoxazole tablets and how long you need to take it depends on the infection you have and how bad it is. Your doctor may prescribe a different dose or length of course of Co-trimoxazole:

- **To treat urinary tract infections:**
- **To treat and prevent lung infections caused by the bacteria Mycoplasma (mimivirus):**
- **To treat infection caused by the protozoa Toxoplasma gondii (toxoplasmosis) or Nocardia (nocardiosis).**

- **If you have kidney problems your doctor may:**
  - **Prescribe a lower dose of Co-trimoxazole tablets:**
  - **Ask you to take the medicine only every second, third or fourth day:**

- **If you have liver problems your doctor may:**
  - **Prescribe a lower dose of Co-trimoxazole tablets:**

- **If you have diabetes your doctor may:**
  - **Prescribe a lower dose of Co-trimoxazole tablets:**

**If you take more Co-trimoxazole than you should**

- **If you take more Co-trimoxazole than you should:**
  - **Talk to your doctor or go to hospital straight away:**
  - **Take the medicine pack with you:**

**If you take more Co-trimoxazole tablets than you should:**

- **If you take more Co-trimoxazole than you should:**
  - **Tell your doctor or go to hospital straight away:**
  - **Take the medicine pack with you:**

**Possible side effects**

- **Like all medicines, this medicine can cause side-effects, although not everybody gets them.**

**Stop taking Co-trimoxazole tablets and tell your doctor immediately if you have an allergic reaction:**

- **Common reactions are more serious than 1 in 10 people are affected:**
  - **Difficulty in breathing:**
  - **Swelling of face, neck or tongue:**
  - **Swallowing difficulty:**
  - **Rash, fever, lower or upper respiratory tract infections:**

**Very common (more than 1 in 10 people):**

- **Common reactions are more serious than 1 in 10 people are affected:**
  - **Nausea:**
  - **Vomiting:**
  - **Diarrhoea:**
  - **Sore throat:**
  - **Rash:**
  - **Onset of skin rash:**

**Common (1 in 10 to 1 in 100 people):**

- **Common reactions are more serious than 1 in 10 people are affected:**
  - **Pain in stomach, which can occur with blood in the stool:**
  - **Pains in your chest, muscles or joints:**
  - **Pain in your stomach:**
  - **Swelling of mouth, tongue or throat:**
  - **Swelling of face:**
  - **Difficulty breathing:**
  - **Hallucinations:**
  - **Confusion:**

**Common reactions are more serious than 1 in 10 people:**

- **Common reactions are more serious than 1 in 10 people are affected:**
  - **Dizziness:**
  - **Fainting:**
  - **Premature menstruation:**
  - **Swelling of hands and feet:**
  - **Muscle weakness:**
  - **Anemia:**
  - **Anaemia:**
  - **Stomach ulcer:**
  - **Nausea:**
  - **Diarrhoea:**
  - **Vomiting:**
  - **Fever:**
  - **Increased skin sensitivity:**
  - **Headache:**
  - **Disorder of taste:**
  - **Disorder of smell:**

**Less common (less than 1 in 10 people):**

- **Less common reactions are more serious than 1 in 10 people are affected:**
  - **Difficulty in breathing:**
  - **Swelling of face, neck or tongue:**
  - **Rash:**
  - **Fever:**
  - **Cough:**
  - **Ringing or other unusual sounds in your ears:**
  - **Inability to speak:**
  - **Tingling or numbness in your hands and feet:**
  - **Muscle pain and/or muscle weakness in HIV patients:**
  - **Cramps:**
  - **Difficulty in swallowing:**
  - **Low levels of sodium in your blood:**
  - **Changes in blood tests:**
  - **Increased blood pressure:**
  - **Asthma:**
  - **Nausea:**
  - **Diarrhoea:**
  - **Vomiting:**
  - **Fever:**
  - **Increased skin sensitivity:**
  - **Headache:**
  - **Disorder of taste:**
  - **Disorder of smell:**

**Rare (less than 1 in 100 people):**

- **Rare reactions are more serious than 1 in 100 people are affected:**
  - **Seizures:**
  - **Increased levels of cholesterol:**
  - **Increased levels of triglycerides:**
  - **Increased liver function tests:**
  - **Increased kidney function tests:**
  - **Muscle pain and/or muscle weakness:**
  - **Cramps:**
  - **Difficulty in swallowing:**
  - **Inability to speak:**
  - **Tingling or numbness in your hands and feet:**
  - **Muscle pain and/or muscle weakness in HIV patients:**
  - **Cramps:**
  - **Difficulty in swallowing:**
  - **Inability to speak:**
  - **Tingling or numbness in your hands and feet:**

**Very rare (less than 1 in 10,000 people):**

- **Very rare reactions are more serious than 1 in 10,000 people are affected:**
  - **Seizures:**
  - **Increased levels of cholesterol:**
  - **Increased levels of triglycerides:**
  - **Increased liver function tests:**
  - **Increased kidney function tests:**
  - **Muscle pain and/or muscle weakness:**
  - **Cramps:**
  - **Difficulty in swallowing:**
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  - **Tingling or numbness in your hands and feet:**
  - **Muscle pain and/or muscle weakness in HIV patients:**
  - **Cramps:**
  - **Difficulty in swallowing:**
  - **Inability to speak:**
  - **Tingling or numbness in your hands and feet:**

**How to store Co-trimoxazole tablets**

**Store Co-trimoxazole tablets:**

- **Below 25°C in a dry place and protect from light:**
  - **Keep out of the sight and reach of children:**
  - **Do not use Co-trimoxazole tablets after the expiry date stated on the label:**

**How to report side effects**

- **If you or anyone else gets side effects:**
  - **Talk to your doctor or go to hospital straight away:**
  - **Take the medicine pack with you:**

**How to report side effects**

- **If you get any side effects:**
  - **Talk to your doctor, pharmacist or nurse:**
  - **This includes possible side effects not listed in this leaflet:**
  - **You can also report side effects directly to the Yellow Card Scheme (which covers medicines and vaccines) or search for MHRA Yellow Cards in the Google Play or Apple App Store:**

**Marketing Authorisation Holder and Manufacturer**

Actavis, Barmstaple, EX32 8NS, UK

The leaflet was reviewed June 2018